Package leaflet: Information for the patient

Fosphenytoin Frost 75 mg/mL (50 mg PE/mL) concentrate for solution for injection/infusion

fosphenytoin sodium

Read all of this leaflet carefully before you are given this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You may have been given this medicine as a single dose to control status epilepticus (a very severe type of seizure). In this case, you will only be able to read this leaflet after you have had the medicine given to you. Your doctor will have considered the important safety information in this leaflet, but your urgent need for treatment may have been more important than some of the normal cautions. Check them now, especially if you are going to continue to be given this medicine (or any other form of phenytoin).

What is in this leaflet

1. What [Product name] is and what it is used for
2. What you need to know before you are given [Product name]
3. How [Product name] is given
4. Possible side effects
5. How to store [Product name]
6. Contents of the pack and other information

1. What [Product name] is and what it is used for

[Product name] contains the active substance fosphenytoin which belongs to a group of medicines called anti-epileptics; these medicines are used to treat epilepsy.

[Product name] is used in **adults and children aged 5 years and older:**
- to contol severe epileptic seizure (fits) so called status epilepticus, of the tonic-clonic (grand mal) type.
- to control or prevent seizures during or after brain surgery and/or head injury.
- to control or prevent seizures for short periods of time when antiepileptic medicines cannot be taken by mouth.

You should talk to your doctor if you are unsure why you have been given this medicine.

2. What you need to know before you are given [Product name]

You must not be given [Product name]
- if you are allergic to fosphenytoin sodium, phenytoin or other similar anti-epileptics or to any of the other ingredients of this medicine (listed in section 6).
- if you have problems with your heart rhythm.
- if you have acute intermittent porphyria (a genetic disorder affecting the formation of red blood cells).
- if you are taking delavirdine, an antiviral medicine used to treat human immunodeficiency virus (HIV) infection.

Tell your doctor if you have had any of these conditions. If you have any questions, ask your doctor, pharmacist or nurse.

Warnings and precautions
Talk to your doctor, pharmacist or nurse before you are given [Product name]; in particular, if you have had any of the following conditions:

- Heart disease or stroke.
- Low blood pressure or heart failure.
- Impaired liver function.
- Impaired kidney function.
- Low protein (albumin) in your blood.
- Special diet which restricts your phosphate intake.
- Diabetes.

Reduced blood pressure and serious heart problems
Reduced blood pressure and serious heart problems may occur during the use of [Product name]. These side effects may be worse in elderly patients, children, or patients who are very ill. Your doctor will therefore monitor your heart, blood preassure and breathing function when you are given this medicine.

Thoughts of harming or killing yourself
A small number of people being treated with anti-epileptics such as fosphenytoin have had thoughts of harming or killing themselves. If at any time you have these thoughts, **immediately contact your doctor**.

Serious skin reactions
In the general population, serious skin side effects can rarely occur during treatment with [Product name]; for signs and symptoms of serious skin reactions and what action to take please see section 4. In people of Chinese or Asian origin this risk may be associated with a variant in genes. If you are of Chinese or Asian origin and tests have shown that you carry the genetic variant HLA- B*1502, or if you are of Taiwanese, Japanese, Malaysian or Thai origin and tests have shown that you carry the genetic variant CYP2C9*3, discuss this with your doctor before taking this medicine.

Allergic reactions
Cases of swelling of the face, mouth (lip, gum, tongue) and throat that can lead to life-threatening breathing difficulty have been reported in people being treated with phenytoin and fosphenytoin. If at any time you have these signs or symptoms immediately contact your doctor.

Risk during pregnancy
There is a risk of harm to the unborn child if [Product name] is used during pregnancy. Women of childbearing age should use effective contraception with [Product name] (see Pregnancy, contraception in women and breast-feeding).

Other medicines and [Product name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Some medicines can affect the way [Product name] works, or [Product name] itself can reduce the effectiveness of other medicines taken at the same time. It is important that your doctor get knowledge of **all other medicines you take**. This includes medicines available with and without prescription (including folic acid and vitamin D) and herbal medicines.

The list below only includes the conditions being treated and not the actual active substances. Your doctor or pharmacist will be able to give you more information.

Talk to your doctor or pharmacist if you take any medicines to treat, prevent or used for:

- heart and circulation problems
- epilepsy
- fungal infections
- human immunodeficiency virus (HIV) infection
- tuberculosis and other infections
- stomach ulcers or heart burn
- asthma and bronchitis (theophylline)
- pain and inflammation
- sleeplessness, depression and psychiatric disorders
- diabetes
- cancer
- rejection in case of organ and tissue transplants or if you take corticosteroids
- hormone replacement therapies (oestrogens), oral contraceptives (the birth control pill) (see Pregnancy, contraception in women, and breast-feeding)
- muscle relaxants used for surgery and some anaesthetic medicines

Your doctor may need to test the amount of phenytoin in your blood to help decide if any of your other medicines may be affecting your treatment.

The herbal preparation St John's wort (*Hypericum perforatum*) should not be taken at the same time as this medicine. If you already take St John's wort, consult your doctor before stopping the St John's wort preparation.

This medicine may also interfere with certain laboratory tests.

[Product name] with alcohol
Drinking a lot of alcohol or drinking frequently can affect the concentration of this medicine in your blood.

Pregnancy, contraception in women and breast-feeding

Pregnancy
If you are pregnant, consult your doctor promptly. You should not stop your treatment until you have discussed this with your doctor. Stopping your medication without consulting your doctor could cause seizures which could be dangerous to you and the pregnancy. Your doctor may decide to change your treatment. Closer monitoring of your unborn child could also be considered.

[Product name] may cause birth defects. If you are given this medicine during pregnancy your baby has a higher risk of having a birth defect. Birth defects which have been reported include facial, skull, nail, finger and heart abnormalities.
If you are of childbearing age and plan to become pregnant, consult your doctor for a preconceptional visit. You should discuss your treatment options with your doctor.
If you are given this medicine during pregnancy, your baby is also at risk for bleeding problems right after birth. Your doctor may give you and your baby a medicine to prevent this. Moreover, your child should be closely monitored.

Contraception in women
If you are of childbearing age, discuss your treatment options and effective methods of birth control with your doctor. This medicine may result in a failure of hormonal contraceptives, hence you should be counselled regarding the use of other effective contraceptive methods.

Breast-feeding
Fosphenytoin passes into breast milk. You should not be given this medicine if you are breast-feeding.

Driving and using machines
This medicine may cause dizziness or drowsiness. If you experience these symptoms, do not drive or use any tools or machinery.

[Product name] contains sodium
When calculating the total amount of sodium, any dilution of fosphenytoin sodium injection with sodium chloride solution should be taken into consideration.

Each 10 ml vial contains 85 mg sodium (main component of cooking/table salt). This is equivalent to 4.25% of the recommended maximum daily dietary intake of sodium for an adult.

3. How [Product name] is given

You will be in hospital when you are given this medicine.

It will be either injected into one of your large veins (intravenous infusion) or into your muscle (intramuscular injection). When given intravenously, this medicine must be diluted.

You will be monitored continuously by electrocardiogram, blood pressure and respiratory function for the duration of the infusion and for approximately 30 minutes after the end of the infusion.

The dose and concentration of the solution of [Product name] you are given will be calculated by your doctor, based on your condition and your weight. The dose will be written as the equivalent dose of phenytoin sodium (PE). This makes it easier for your doctor to calculate the dose when substituting fosphenytoin for phenytoin or vice versa. The dose will be as milligram per dose if given as an injection or milligram per millilitre (mg/ml) of solution if given as an infusion.

Use in adults

- **Severe epileptic seizure or fits (Status epilepticus)**
  [Product name] is usually given after treatment with diazepam or lorazepam injection.

  The first dose of [Product name] is called a loading dose and is injected into your vein. After the loading dose you may receive lower doses of this medicine, intravenously or intramuscularly. These are called maintenance doses.

  If this medicine does not stop your seizures (fits), other treatments will be tried.

- **Brain surgery or head trauma**
  The first dose is called a loading dose and is injected into your vein or into your muscle. After the loading dose you may receive lower doses of [Product name], intravenously or intramuscularly. These are called maintenance doses.

  Maintenance doses
  Your doctor may take samples of your blood to help decide the right maintenance dose for you.

  If your doctor decides that you need to continue treatment, you will be transferred to treatment by mouth when appropriate. This will be with phenytoin because this medicine (fosphenytoin) cannot be taken by mouth.

- **Temporary replacement of oral phenytoin treatment**
  If you are given [Product name] because you cannot take phenytoin by mouth, you will not need a loading dose and the dose you are given will be the same as your dose of phenytoin. Because the dose of fosphenytoin is given in PE (phenytoin sodium equivalents), the number of milligrams PE of [Product name] you are given should be the same as the number of milligrams of phenytoin sodium you take by mouth.

Use in children aged 5 years and older
The doses of [Product name] per kilogram of body weight are the same for children (aged 5 years and older) as for adults.

This medicine is given to children aged 5 years and older by a drip (infusion) into the vein (intravenous) only.

Use in elderly patients over 65 years, the very ill and patients with kidney or liver disease
The dose of this medicine may be reduced or the injection given into the vein at a slower rate.

If you are given more [Product name] than you should
An overdose of [Product name] is dangerous. However, this medicine is given to you in a hospital and the dose is calculated for you individually and the doctor will monitor you during treatment and cardiac resuscitative equipment will be available.
If you think you have been given too much of this medicine, contact your doctor immediately.
If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Contact a doctor immediately if you experience any of the following symptoms after been given this medicine. Although they may be uncommon, these symptoms can be serious.

Uncommon: may affect up to 1 in 100 people
- If you develop a severe skin rash that causes blistering, (this can also affect the mouth and tongue). These skin reactions are often accompanied by fever or flu-like symptoms. This may be signs of a condition known as Stevens Johnson Syndrome, or toxic epidermal necrolysis (TEN). Your doctor will stop your treatment in these cases.

Not known: frequency cannot be estimated from the available data
- If you notice **bruising, fever, you are looking pale or a severe sore throat**. These may be the first signs of an abnormality of the blood, such as decreases in the number of red cells, white cells or platelets. Your doctor may take regular blood samples to test your blood counts.
- **Skin rash and fever with swollen glands, yellow skin and eyes**, particularly in the first two months of treatment, as these may be signs of a hypersensitivity reaction. If these are severe and you also experience pain and inflammation of the joints this could be related to a condition called systemic lupus erythematosus.
- If you experience **skin discolouration, swelling and pain** where the injection was given which then starts to spread down your arm to your hands and fingers. This may mean you have a condition known as “purple glove syndrome”. In most cases this will improve on its own but in some cases it can be serious and require urgent medical treatment.
- Areas of red skin with small elevated **sterile pustules (small blisters filled with white/yellow fluid)**. There tends to be more disease in skin folds. Swelling of the face can occur as well (Acute Generalized Exanthematous Pustulosis [AGEP]).
- **Skin rash, fever, swollen glands, increase in a type of white blood cell (eosinophilia), and inflammation of internal organs** (liver, lungs, heart, kidneys and large intestine), as they may be signs of a hypersensitivity reaction (Drug Reaction with Eosinophilia and Systemic Symptoms [DRESS]).
- If you experience a state of **confusion or severe mental illness**, as this may be a sign that you have high amounts of phenytoin in your blood. On rare occasions, when the amount of phenytoin

in the blood remains high, irreversible brain injury has occurred. Your doctor may test your blood to see how much phenytoin is in the blood and may change your dose.
- **Sudden wheeziness, difficulty in breathing, swelling of eyelids, face or lips, rash or itching** (especially affecting the whole body) as this may be a sign of a hypersensitivity reaction.

Other side-effects that may occur are:

Very common: may affect more than 1 in 10 people
- unusual eye movements, dizziness.

Common: may affect up to 1 in 10 people
- mood swings, pins and needles, unsteadiness, drowsiness, headaches, shaking, abnormal or uncoordinated movements, slurred speech, blurred vision.
- ringing in the ears, vertigo.
- feeling sick, dry mouth, being sick.
- pain or reaction at the site of injection.
- loss of energy or strength, chills.

Uncommon: may affect up to 1 in 100 people
- nervousness, confusion, abnormal/irrational thoughts.
- numbness.
- double vision, loss of hearing.
- loss of sensation in the tongue.
- skin rash including measles-like reactions which are mild.
- muscle weakness, twitching muscles, painful muscles.

Not known: frequency cannot be estimated from the available data
- hives
- swelling of the lymph glands.
- inflammation of the wall of the arteries, problems with the body's defence against infection.
- increased levels of blood sugar, or decreased levels of blood calcium, folic acid and vitamin D. If you also do not get enough vitamin D in your diet or from exposure to sunlight, you may suffer from bone pain or fractures.
- There have been reports of bone disorders including osteopenia and osteoporosis (thinning of the bone) and fractures. Check with your doctor or pharmacist if you are on long-term anti-epileptic medicines, have a history of osteoporosis, or take steroids.
- change in appetite, difficulty in controlling movements, sleeplessness, convulsions.
- inflammation of the lining of the lung, problems breathing.
- enlarged gums, constipation.
- inflammation of the liver, liver damage (seen as yellowing of the skin and whites of the eye).
- increased or abnormal body or facial hair, changes in facial features, enlarged lips, changes in the hands with difficulty in straightening the fingers.
- inflammation of the kidneys.
- temporary itching, burning, warmth or tingling in the groin may sometimes occur during or shortly after injection of fosphenytoin into your vein. Your doctor may reduce the rate at which fosphenytoin is injected or temporarily stop injecting fosphenytoin if you feel these sensations.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system <to be completed nationally>. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store [Product name]

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and vial after 'EXP'. The expiry date refers to the last day of that month.

Store in a refrigerator (2°C – 8°C).

Chemical and physical in-use stability has been demonstrated for 4 hours at 25°C for the diluted product. From a microbiological point of view, unless the method of dilution precludes the risk of microbial contamination, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of user.

For single use only. After opening, unused product should be discarded.

Vials that contain particulate matter should not be used.

Any unused medicine should be disposed of in line with local requirements.

6. Contents of the pack and other information

What [Product name] contains

- The active substance is fosphenytoin sodium. One ml of [Product name] contains 75 mg of fosphenytoin sodium. This is equivalent to 50 mg phenytoin sodium (50 mg PE).
  The 10 ml vial contains 750 mg of fosphenytoin sodium (equivalent to 500 mg phenytoin sodium and referred to as 500 mg PE).
- The other excipients are trometamol, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment) and water for injection

What [Product name] looks like and contents of the pack

[Product name] concentrate for solution for injection/infusion comes in a small glass bottle (vial) of clear glass with grey rubber stopper and aluminium cap containing 10 ml of sterile solution. The solution is clear, colourless to pale yellow.

[Product name] is available in packs containing a single vial with 10 ml solution or in packs containing 10 vials with 10 ml solution. Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This leaflet was last revised in 2022-09-20

The following information is intended for healthcare professionals only

DOSING AID for [Product name] (fosphenytoin) in Status Epilepticus
For Adults Only

There have been deaths due to medication errors with fosphenytoin.

Instructions for use: This dosing aid is designed to help you administer a loading dose of fosphenytoin. Use the equations and/or consult the dosing table below to determine the appropriate dosing information based on patient weight.

ADULT ONLY DOSING
Refer to the summary of product characteristics (SmPC) for full prescribing details.

Take care to ensure that the correct dose of fosphenytoin is administered.

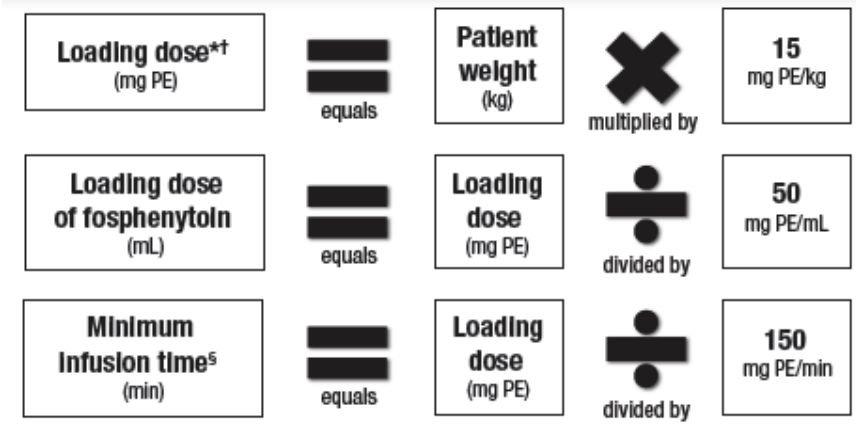
Note that:
1. Each 10 mL vial of fosphenytoin contains 500 mg PE.
   PE = phenytoin sodium equivalents.
2. Fosphenytoin should always be prescribed and dispensed in mg PE.

Administration of the loading dose
1. Administer 15 milligrams phenytoin sodium equivalents (PE) per kilogram (15 mg PE/kg) as a single dose by intravenous (IV) infusion.
   - For IV infusion, dilute the dose in a solution of 5% glucose or in a solution of 0.9% sodium chloride.
   - The rate of infusion should not exceed 150 mg PE/min for adults.
2. It is essential to monitor ECG, blood pressure and respiratory function during and after fosphenytoin infusion (particularly in the first 30 minutes following administration). Cardiac resuscitative equipment should be available.
3. For elderly patients and patients with renal or hepatic disease, consider a lower loading dose and/or infusion rate (10%-25% reduction). Careful clinical monitoring is required.

See the table below for infusion times.

PLEASE NOTE: this dosing guide is for use for the emergency treatment of status epilepticus only. Consult the SmPC for guidance on maintenance dosing.

Loading doses, diluent volumes and infusion times per patient weight in kg.



*Loading dose may require opening more than one vial. See package details.
†Before IV administration, add diluent in volume that is equal to the volume of loading dose of fosphenytoin in mL.
§Infusion time is critical due to risk for cardiovascular events.
Please use the table below to confirm all your calculations.

Adult					
	Loading dose of fosphenytoin				
Patient weight (kg)	in milligrams phenytoin sodium equivalents (mg PE)	in milliliters of fosphenytoin (mL)	Number of vials required	Volume of diluent to add (mL)	Minimum infusion time (min)
120[a]	1800	36	3 full + 1 partial	36	12
119	1785	35.7	3 full + 1 partial	35.7	12
118	1770	35.4	3 full + 1 partial	35.4	12
117	1755	35.1	3 full + 1 partial	35.1	12
116	1740	34.8	3 full + 1 partial	34.8	12
115	1725	34.5	3 full + 1 partial	34.5	12
114	1710	34.2	3 full + 1 partial	34.2	12
113	1695	33.9	3 full + 1 partial	33.9	12
112	1680	33.6	3 full + 1 partial	33.6	12
111	1665	33.3	3 full + 1 partial	33.3	12
110	1650	33	3 full + 1 partial	33	11
109	1635	32.7	3 full + 1 partial	32.7	11
108	1620	32.4	3 full + 1 partial	32.4	11
107	1605	32.1	3 full + 1 partial	32.1	11
106	1590	31.8	3 full + 1 partial	31.8	11
105	1575	31.5	3 full + 1 partial	31.5	11
104	1560	31.2	3 full + 1 partial	31.2	11
103	1545	30.9	3 full + 1 partial	30.9	11
102	1530	30.6	3 full + 1 partial	30.6	11
101	1515	30.3	3 full + 1 partial	30.3	11
100	1500	30	3 full	30	10
99	1485	29.7	2 full + 1 partial	29.7	10
98	1470	29.4	2 full + 1 partial	29.4	10
97	1455	29.1	2 full + 1 partial	29.1	10
96	1440	28.8	2 full + 1 partial	28.8	10
95	1425	28.5	2 full + 1 partial	28.5	10
94	1410	28.2	2 full + 1 partial	28.2	10
93	1395	27.9	2 full + 1 partial	27.9	10
92	1380	27.6	2 full + 1 partial	27.6	10
91	1365	27.3	2 full + 1 partial	27.3	10
90	1350	27	2 full + 1 partial	27	9
89	1335	26.7	2 full + 1 partial	26.7	9
88	1320	26.4	2 full + 1 partial	26.4	9
87	1305	26.1	2 full + 1 partial	26.1	9
86	1290	25.8	2 full + 1 partial	25.8	9
85	1275	25.5	2 full + 1 partial	25.5	9
84	1260	25.2	2 full + 1 partial	25.2	9
83	1245	24.9	2 full + 1 partial	24.9	9
82	1230	24.6	2 full + 1 partial	24.6	9
81	1215	24.3	2 full + 1 partial	24.3	9
80	1200	24	2 full + 1 partial	24	8
79	1185	23.7	2 full + 1 partial	23.7	8
78	1170	23.4	2 full + 1 partial	23.4	8
77	1155	23.1	2 full + 1 partial	23.1	8
76	1140	22.8	2 full + 1 partial	22.8	8
75	1125	22.5	2 full + 1 partial	22.5	8
74	1110	22.2	2 full + 1 partial	22.2	8
73	1095	21.9	2 full + 1 partial	21.9	8
72	1080	21.6	2 full + 1 partial	21.6	8
71	1065	21.3	2 full + 1 partial	21.3	8

70	1050	21	2 full + 1 partial	21	7
69	1035	20.7	2 full + 1 partial	20.7	7
68	1020	20.4	2 full + 1 partial	20.4	7
67	1005	20.1	2 full + 1 partial	20.1	7
66	990	19.8	1 full + 1 partial	19.8	7
65	975	19.5	1 full + 1 partial	19.5	7
64	960	19.2	1 full + 1 partial	19.2	7
63	945	18.9	1 full + 1 partial	18.9	7
62	930	18.6	1 full + 1 partial	18.6	7
61	915	18.3	1 full + 1 partial	18.3	7
60	900	18	1 full + 1 partial	18	6
59	885	17.7	1 full + 1 partial	17.7	6
58	870	17.4	1 full + 1 partial	17.4	6
57	855	17.1	1 full + 1 partial	17.1	6
56	840	16.8	1 full + 1 partial	16.8	6
55	825	16.5	1 full + 1 partial	16.5	6
54	810	16.2	1 full + 1 partial	16.2	6
53	795	15.9	1 full + 1 partial	15.9	6
52	780	15.6	1 full + 1 partial	15.6	6
51	765	15.3	1 full + 1 partial	15.3	6
50	750	15	1 full + 1 partial	15	5
49	735	14.7	1 full + 1 partial	14.7	5
48	720	14.4	1 full + 1 partial	14.4	5
47	705	14.1	1 full + 1 partial	14.1	5
46	690	13.8	1 full + 1 partial	13.8	5
45	675	13.5	1 full + 1 partial	13.5	5
44[a]	660	13.2	1 full + 1 partial	13.2	5

[a]See ‘Administration of the loading dose’ above for patients who weigh <44 kg or >120 kg.
Please refer to the summary of product characteristics (SmPC) for full prescribing details.

DOSING AID for [Product name] (fosphenytoin) in Status Epilepticus
For children 5 years and older

There have been deaths due to medication errors with fosphenytoin.

DO NOT administer to children under 5 year of age

Instructions for use: This dosing aid is designed to help you administer a loading dose of fosphenytoin. Use the equations and/or consult the dosing table below to determine the appropriate dosing information based on patient weight.

ONLY FOR CHILDREN 5 YEARS AND OLDER
Refer to the summary of product characteristics (SmPC) for full prescribing details.

Take care to ensure that the correct dose of fosphenytoin is administered.

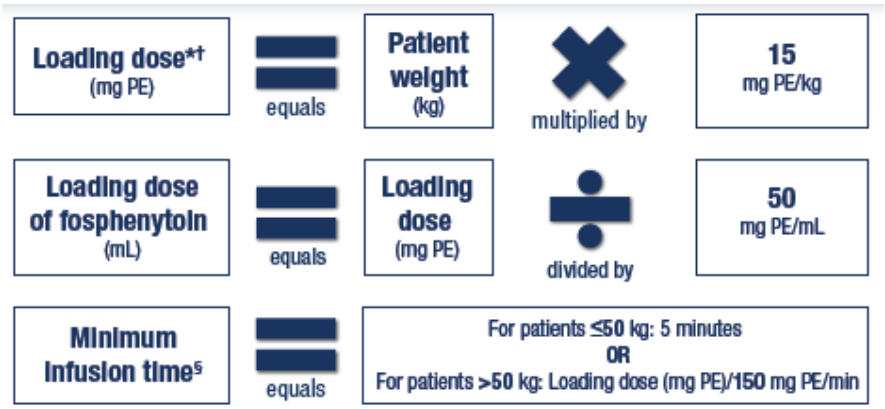
Note that:
1. Each 10 mL vial of fosphenytoin contains 500 mg PE.
   PE = phenytoin sodium equivalents.
2. Fosphenytoin should always be prescribed and dispensed in mg PE.

Administration of the loading dose
1. The loading dose of fosphenytoin is 15 milligrams phenytoin sodium equivalents (PE) per kilogram (15 mg PE/kg) administered as a single dose by intravenous (IV) infusion. Intramuscular administration is not recommended.
   - Recommended IV infusion rate is 2 to 3 mg PE/kg/min. **Should not exceed 3 mg PE/kg/min.**
   - For IV infusion, dilute the dose in a solution of 5% glucose or 0.9% sodium chloride.
2. It is essential to monitor ECG, blood pressure and respiratory function during and after fosphenytoin infusion (particularly in the first 30 minutes following administration). Cardiac resuscitative equipment should be available.
3. For patients with renal or hepatic disease, consider a lower loading dose and/or infusion rate (10%-25% reduction). Careful clinical monitoring is required.

See the table below for infusion times.

PLEASE NOTE: this dosing guide is for use for the emergency treatment of status epilepticus only. Consult the SmPC for guidance on maintenance dosing.

Loading doses, diluent volumes and infusion times per patient weight in kg.



*Loading dose may require opening more than one vial. See package details.
†Before IV administration, add diluent in volume that is equal to the volume of loading dose of fosphenytoin in mL.

§Infusion time is critical due to risk for cardiovascular events.

Please use the table below to confirm all your calculations.

Children 5 years and older					
Patient weight (kg)	Loading dose of fosphenytoin			Volume of diluent to add (mL)	Minimum infusion time (min)
	in milligrams phenytoin sodium equivalents (mg PE)	in milliliters of fosphenytoin (mL)	Number of vials required		
44[a]	660	13.2	1 full + 1 partial	13.2	5
43	645	12.9	1 full + 1 partial	12.9	5
42	630	12.6	1 full + 1 partial	12.6	5
41	615	12.3	1 full + 1 partial	12.3	5
40	600	12	1 full + 1 partial	12	5
39	585	11.7	1 full + 1 partial	11.7	5
38	570	11.4	1 full + 1 partial	11.4	5
37	555	11.1	1 full + 1 partial	11.1	5
36	540	10.8	1 full + 1 partial	10.8	5
35	525	10.5	1 full + 1 partial	10.5	5
34	510	10.2	1 full + 1 partial	10.2	5
33	495	9.9	1 partial	9.9	5
32	480	9.6	1 partial	9.6	5
31	465	9.3	1 partial	9.3	5
30	450	9	1 partial	9	5
29	435	8.7	1 partial	8.7	5
28	420	8.4	1 partial	8.4	5
27	405	8.1	1 partial	8.1	5
26	390	7.8	1 partial	7.8	5
25	375	7.5	1 partial	7.5	5
24	360	7.2	1 partial	7.2	5
23	345	6.9	1 partial	6.9	5
22	330	6.6	1 partial	6.6	5
21	315	6.3	1 partial	6.3	5
20	300	6	1 partial	6	5
19	285	5.7	1 partial	5.7	5
18	270	5.4	1 partial	5.4	5
17[a]	255	5.1	1 partial	5.1	5

[a]See ‘Administration of the loading dose’ above for patients who weigh <17 kg or >44 kg.
Please refer to the summary of product characteristics (SmPC) for full prescribing details.